

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

**UNITED STATES OF AMERICA, *et al.*,
ex rel. MATTHEW A. FITZER, M.D.,**

Plaintiffs,

v.

ALLERGAN, INC., *et al.*

Defendants.

Civil Case No. 1:17-cv-00668-SAG

* * * * *

MEMORANDUM OPINION

Relator Matthew A. Fitzer (“Relator”) filed an initial complaint against Defendant Allergan, Inc. (“Allergan”), under seal, in November, 2013, alleging that Allergan conducted an unlawful kickback scheme in violation of the False Claims Act (“FCA”), 31 U.S.C. § 3729, *et seq.* ECF 1. In August, 2014, Relator filed an Amended Complaint adding Defendant Apollo Endosurgery, Inc. (individually, “Apollo” and collectively with Allergan “Defendants”). ECF 6. In February, 2021, after the United States declined to intervene, ECF 48, this Court unsealed the case, ECF 49, and Relator filed a Second Amended Complaint (“SAC”), ECF 77. Both Defendants have filed motions to dismiss the SAC (collectively, the “Motions”) under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. ECF 80, 82. Allergan’s motion also argues for dismissal under Federal Rule of Civil Procedure 12(b)(1) because, in its view, the Court lacks subject matter jurisdiction. ECF 82. The Court has reviewed the Motions, both of Relator’s oppositions, ECF 86, 87, and Defendants’ replies, ECF 89, 90. No hearing is necessary. *See* Loc. R. 105.6 (D. Md. 2021). For the reasons set forth below, Defendants’ Motions will be granted, and the SAC will be dismissed without prejudice.

I. FACTUAL BACKGROUND

The facts described herein, and alleged in the SAC, are assumed to be true for purposes of adjudicating Defendants' Motions. Defendants are two medical device companies who have, at different times, owned the LAP-BAND brand. ECF 77 ¶¶ 47, 51. The LAP-BAND is a surgically implanted device used for the treatment of obesity. *Id.* ¶ 97. Once implanted, the LAP-BAND fits around the stomach, allowing physicians to "adjust digestive function in a manner intended to reduce hunger and lessen the amount of food required to feel satisfaction." *Id.* ¶ 98.

At different times, both Defendants used the website www.lapband.com to advertise and market the LAP-BAND product. *Id.* ¶ 111. Among other features, the website included a physician locator that allowed potential patients to input their zip codes to identify bariatric surgeons in their area who could perform the surgery required to implant the LAP-BAND device. *Id.* ¶ 114. The locator would provide the prospective patient with a link to the local surgeons' websites and, for a period of time, their seminar schedules where patients could enroll in seminars and meet the surgeons listed on the website. *Id.* ¶¶ 114-15, 117-18.

Relator alleges that the website became a powerful tool for patients to find surgeons who could perform LAP-BAND surgery and, in turn, "provided a constant flow of business to the included surgeons." *Id.* ¶ 121, 123. However, Relator also alleges that Defendants used the physician locator to conduct "an unlawful kickback scheme . . . by providing surgeons with valuable free advertising on [the website] in order to induce surgeons to recommend Defendants' LAP-BAND medical device instead of alternative operations." *Id.* ¶ 2. Central to Relator's theory, he alleges that Defendants implemented a quota of LAP-BAND surgeries that a physician needed to perform per year to be included on the physician locator. *Id.* ¶¶ 7-8.

Relator is a bariatric surgeon qualified to perform all three of the major bariatric operations: gastric bypass, sleeve gastrectomy, and gastric band surgery. *Id.* ¶ 31. He learned about the LAP-BAND website and its physician locator at a practice development seminar in February, 2012. *Id.* ¶ 129-30. At the seminar, he was told that the website was “a very valuable promotional resource” and that he should contact Allergan if he was interested in being included. *Id.* ¶ 130. The next month, Relator met with an Allergan Account Manager and “asked to be included in the database for referrals by www.lapband.com.” *Id.* ¶ 133-34. The Account Manager asked Relator some questions about “his decision-making process with regard to recommending a LAP-BAND implant as opposed to other kinds of surgery[,]” and “what would make him decide to do a LAP-BAND procedure and in what percentage of these cases he would be likely to do a LAP-BAND implant.” *Id.* ¶¶ 135-36. The Account Manager told Relator he would be “granted access to the website” and “added to the physician locator.” *Id.* ¶ 137.

Relator was added to the physician locator in June, 2012. *Id.* ¶ 142. Despite immediately receiving an increase in patient interest attributable to the physician locator, *id.*, he experienced “problematic and unexplained gaps in service in his account[,]” *id.* ¶ 143, that he believes “resulted from Allergan’s dissatisfaction with his LAP-BAND productivity.” *Id.* ¶ 144. A few months later, he was temporarily “locked out” of his www.lapband.com account. *Id.* ¶ 146-47. To Relator’s knowledge, no LAP-BAND-only surgeons (surgeons who, unlike Relator, only perform LAP-BAND surgeries but not the other mainstream bariatric surgeries) experienced disruptions to their accounts. *Id.* ¶ 148-49.

In March, 2013, Relator was removed from the physician locator and was denied access to the website. *Id.* ¶ 153. Relator contacted his Allergan Account Manager who promised to investigate the matter. *Id.* ¶ 155-56. The two spoke on the phone two days later, and the Account

Manager informed Relator that he had been removed from the physician locator because he “had not conducted at least 40 LAP-BAND procedures in a year.” *Id.* ¶ 161. The following day, Relator contacted Allergan’s Vice President of Sales and informed him that, in Relator’s view, the quota violated federal law, including the Anti-Kickback Statute (“AKS”). *Id.* ¶ 167. Relator later spoke on the phone with the Vice President of Sales who confirmed that only surgeons who performed 40 LAP-BAND surgeries per year were included on the website’s physician locator and that the requirement was “related to ‘quality.’” *Id.* ¶¶ 171-72, 176. Relator has never been reinstated on the physician locator. *Id.* ¶ 158.

Apollo purchased the LAP-BAND brand in or around December, 2013. *Id.* ¶ 51. Apollo maintained a quota for inclusion on the physician locator through at least 2018. *Id.* ¶ 193.

II. LEGAL STANDARD

Under Rule 12(b)(6), a defendant may test the legal sufficiency of a complaint by way of a motion to dismiss. *See In re Birmingham*, 846 F.3d 88, 92 (4th Cir. 2017); *Goines v. Valley Cmty. Servs. Bd.*, 822 F.3d 159, 165–66 (4th Cir. 2016); *McBurney v. Cuccinelli*, 616 F.3d 393, 408 (4th Cir. 2010), *aff’d sub nom.*, *McBurney v. Young*, 569 U.S. 221 (2013); *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999). A Rule 12(b)(6) motion constitutes an assertion by a defendant that, even if the facts alleged by a plaintiff are true, the complaint fails as a matter of law “to state a claim upon which relief can be granted.”

Whether a complaint states a claim for relief is assessed by reference to the pleading requirements of Federal Rule of Civil Procedure 8(a)(2). That rule provides that a complaint must contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” The purpose of the rule is to provide the defendants with “fair notice” of the claims and the “grounds” for entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007).

To survive a motion under Federal Rule of Civil Procedure 12(b)(6), a complaint must contain facts sufficient to “state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570; *see Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009) (“Our decision in *Twombly* expounded the pleading standard for all civil actions[.]”) (quotation omitted); *see also Willner v. Dimon*, 849 F.3d 93, 112 (4th Cir. 2017). However, a plaintiff need not include “detailed factual allegations” in order to satisfy Rule 8(a)(2). *Twombly*, 550 U.S. at 555. Further, federal pleading rules “do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted.” *Johnson v. City of Shelby, Miss.*, 574 U.S. 10, 11 (2014) (per curiam).

Nevertheless, the rule demands more than bald accusations or mere speculation. *Twombly*, 550 U.S. at 555; *see Painter’s Mill Grille, LLC v. Brown*, 716 F.3d 342, 350 (4th Cir. 2013). If a complaint provides no more than “labels and conclusions” or “a formulaic recitation of the elements of a cause of action,” it is insufficient. *Twombly*, 550 U.S. at 555. Rather, to satisfy the minimal requirements of Rule 8(a)(2), the complaint must set forth “enough factual matter (taken as true) to suggest” a cognizable cause of action, “even if . . . [the] actual proof of those facts is improbable and . . . recovery is very remote and unlikely.” *Twombly*, 550 U.S. at 556.

In addition to the plausibility standard set forth in *Twombly*, fraud-based claims are subject to heightened pleading requirements set forth in Federal Rule of Civil Procedure 9(b). Rule 9(b) requires a plaintiff to “state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). However, “[m]alice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” *Id.*

In reviewing a Rule 12(b)(6) motion, a court “must accept as true all of the factual allegations contained in the complaint” and must “draw all reasonable inferences [from those facts] in favor of the plaintiff.” *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 440

(4th Cir. 2011) (citations omitted); *see Semenova v. MTA*, 845 F.3d 564, 567 (4th Cir. 2017); *Houck v. Substitute Tr. Servs., Inc.*, 791 F.3d 473, 484 (4th Cir. 2015); *Kendall v. Balcerzak*, 650 F.3d 515, 522 (4th Cir. 2011), *cert. denied*, 565 U.S. 943 (2011). However, a court is not required to accept legal conclusions drawn from the facts. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986). “A court decides whether [the pleading] standard is met by separating the legal conclusions from the factual allegations, assuming the truth of only the factual allegations, and then determining whether those allegations allow the court to reasonably infer” that the plaintiff is entitled to the legal remedy sought. *A Soc’y Without a Name v. Virginia*, 655 F.3d 342, 346 (4th Cir. 2011), *cert. denied*, 566 U.S. 937 (2012).

III. ANALYSIS

Defendants seek dismissal for failure to state a claim. Allergan’s motion argues for dismissal on the additional ground that the Court lacks subject matter jurisdiction because the FCA’s first-to-file bar precludes Relator from pursuing his claims against Allergan. While this Court finds that the first-to-file bar does not prevent this Court from exercising jurisdiction over Relator’s claims, it finds that dismissal is warranted because the SAC fails to state a claim.

A. First-to-File Bar

The FCA provides that, “[w]hen a person brings an [FCA action], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). This provision is known as the “first-to-file bar,” and it “functions both to eliminate parasitic plaintiffs who piggyback off the claims of a prior relator, and to encourage legitimate relators to file quickly by protecting the spoils of the first to bring a claim.” *United States ex rel. Palmieri v. Alpharma, Inc.*, No. ELH-10-1601, 2016 WL 7324629, at *7 (D. Md. Dec. 16, 2016) (quoting *In re Nat. Gas Royalties Qui Tam Litig.*, 566 F.3d 956, 961 (10th Cir. 2009)). The Fourth Circuit recognizes the first-to-file bar as a jurisdictional requirement,

meaning that any complaint found to violate the bar must be dismissed for lack of subject matter jurisdiction. *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013), *aff'd in part rev'd in part on other grounds, Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 575 U.S. 650 (2015). The Fourth Circuit has described the bar as an “absolute, unambiguous exception-free rule.” *Id.*

To evaluate whether a complaint violates the first-to-file bar, the Fourth Circuit applies a “same material elements test.” *Id.* at 182. That test bars a later suit if it “is based upon the ‘same material elements of fraud’ as the earlier suit, even though the subsequent suit may ‘incorporate somewhat different details.’” *Id.* (quoting *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1189 (9th Cir. 2011)). In other words, if an action is “based on the same ‘material facts’ or the same ‘essential facts’ as the pending action,” it is barred even if the later suit is not based on “identical facts.” *Palmieri*, 2016 WL 7324629, at *8 (emphasis in original) (quoting *United States ex rel. Chovanec v. Apria Healthcare Grp. Inc.*, 606 F.3d 361, 363 (7th Cir. 2010)). “The test prevents the less vigilant whistle-blower from using insignificant factual variations to allege what is essentially the same fraudulent scheme already made known to the government.” *Carter*, 710 F.3d at 182 (quoting *United States ex rel. Folliard v. Synnex Corp.*, 798 F. Supp. 2d 66, 73 (D.D.C. 2011)).

Here, Allergan argues that Relator’s claims are barred by the first-to-file rule because his initial complaint was filed while another *qui tam* FCA suit was pending against Allergan asserting AKS and FCA violations related to Allergan’s LAP-BAND promotional practices. ECF 82-1 at 12-17. That case, *United States ex rel. Schwartz v. Allergan, Inc.*, No. 10-cv-02796 (D. Md.), was filed in October, 2010 and ultimately settled, after the Government’s intervention, in 2018.

Schwartz, ECF 87-92.¹ A close comparison of the two cases, however, reveals that they were not “based on the same ‘material facts[.]’” *Palmieri*, 2016 WL 7324629, at *8 (emphasis in original) (quoting *Chovanec*, 606 F.3d at 363).

In *Schwartz*, two relators—one of whom was a former sales representative for Allergan and one of whom was a bariatric surgeon with experience implanting the LAP-BAND—brought AKS and FCA claims based on allegations of an elaborate scheme by Allergan to conceal from the public that the LAP-BAND had a design defect that was harming patients. *Schwartz*, ECF 18 ¶ 3. The LAP-BAND is expanded and restricted by injecting or removing saline solution through an access port “placed under the skin in the patient’s chest wall that connects to the band through tubing.” *Id.* ¶ 2. The relators in *Schwartz* alleged that the defective access port was causing fluid to leak. *Id.* ¶¶ 3. The relators alleged that Allergan failed to notify doctors, patients, or the Food and Drug Administration (“FDA”) after discovery of the design defect, in order to avoid a recall

¹ The parties argue, at length, about whether the Court may rely on or take judicial notice of certain materials, extraneous to the SAC, that were either attached as exhibits to Allergan’s Motion or cited in Apollo’s. It is well settled that, for purposes of evaluating a motion to dismiss for lack of subject matter jurisdiction, the Court may consider materials outside the pleadings without converting the motion to a motion for summary judgment. *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991). Thus, the Court may properly consider the publicly filed documents in *Schwartz* to evaluate whether the first-to-file bar requires dismissal. The same is not true, however, for motions to dismiss based on failure to state a claim. Ordinarily, on a motion to dismiss for failure to state a claim, consideration of documents outside the pleadings would require the Court to convert the motion to a motion for summary judgment unless those materials are expressly referenced or relied upon in the pleadings. *See Tucker v. Specialized Loan Servicing, LLC*, 83 F. Supp. 3d 635, 648 (D. Md. 2015) (quoting *CACI Int’l v. St. Paul Fire & Marine Ins. Co.*, 566 F.3d 150, 154 (4th Cir. 2009) for the proposition that the Court can consider a “document that the defendant attaches to its motion to dismiss if the document was integral to and explicitly relied on in the complaint and if the plaintiffs do not challenge its authenticity.”). The Court may also consider “matters of which a court may take judicial notice.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). None of the extraneous materials on which Defendants rely is central to the Court’s analysis or ultimate decision on these Motions, and the Court has not considered those materials. Accordingly, the Court need not decide whether it could properly consider those materials at this stage. For the same reason, Allergan’s “Request for Judicial Notice,” ECF 83, is denied.

of the LAP-BAND. *Id.* ¶ 5. The *Schwartz* relators also alleged that Allergan “offered financial inducements to doctors for the purpose of getting them to continue to prescribe and use the LAP-BAND despite this known defect in the access port[,]” and that Allergan “engaged in a course of conduct to conceal the defect from the public, physicians and the FDA including making payments to physicians not to report the defect and lying to the public and to physicians about the cause of the leaking access ports.” *Id.* ¶ 6. Further, the *Schwartz* relators alleged that Allergan unlawfully paid physicians “for the purpose of inducing sales of LAP-BANDs” and “unlawfully promoted off-label uses of the LAP-BAND.” *Id.* ¶ 8.

In the course of Allergan’s alleged fraudulent scheme to cover up the defective access port, the *Schwartz* relators alleged—similar to the allegations Relator makes here—that Allergan provided remuneration to physicians in many forms, including valuable marketing and advertising. *See id.* ¶¶ 73, 205. Moreover, those relators alleged that Allergan retaliated against Dr. Schwartz—after he attempted to blow the whistle on Allergan’s cover up—by removing him from the LAP-BAND website. *Id.* ¶¶ 151, 202.

Here, Allergan argues that the first-to-file bar precludes this Court from adjudicating Relator’s claims because they contain the same “material elements” of the fraud alleged in *Schwartz*. ECF 82-1 at 12-17. According to Allergan, “the allegations in *Schwartz* plainly equipped the Government with ‘enough knowledge of essential facts’ to ‘discover’ the fraud alleged in Relator’s lawsuit.” *Id.* at 16 (quoting *Carter*, 710 F.3d at 182). This Court disagrees.

The fraud alleged in *Schwartz* was different in-kind than the fraud Relator alleges here. It focused on a defective product and an elaborate and fraudulent scheme to cover it up. By contrast, the allegations here focus exclusively on Defendants’ operation of the LAP-BAND website and their alleged use of that website to drive sales of the LAP-BAND device through the website’s

physician locator tool. Those are not the “same ‘*material* facts’” that merely “incorporate somewhat different details.” *Palmieri*, 2016 WL 7324629, at *8 (emphasis in original) (quoting *Chovanec*, 606 F.3d at 363); *Carter*, 710 F.3d at 182. They are two entirely different fraudulent schemes. Relator here, therefore, is not “using insignificant factual variations to allege what is essentially the same fraudulent scheme already made known to the government.” *Carter*, 710 F.3d at 182 (quoting *Folliard*, 798 F. Supp. 2d at 73). The mere fact that the amended complaint in *Schwartz* referenced Allergan’s use of the LAP-BAND website to drive sales is not a sufficient overlap to put the Government on notice of the fraud Relator alleges here or to preclude his claims under the first-to-file bar. The bar exists to prevent multiple *qui tam* suits focused on the same conduct, not to preclude two suits that focus on entirely different conduct, but which both happen to involve the use of the same website. Accordingly, the first-to-file bar does not divest this Court of jurisdiction over Relator’s claims.²

B. Defendants’ Motions to Dismiss for Failure to State a Claim

i. Relator’s Theory of Liability Under the AKS and the FCA

The FCA imposes liability on anyone who, in relevant part, “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval[.]” or anyone who “knowingly

² The parties argue about the import of the settlement agreement in *Schwartz* wherein the Government—in an apparent reference to Relator’s First Amended Complaint which was pending under seal at the time—expressly reserved claims “regarding the web-based locator tool on the LAP-BAND website[.]” *Schwartz*, ECF 87-1 at 9. Allergan argues that the Government’s reservation of those claims “acknowledg[ed] the overlap between *Schwartz* and this case[.]” ECF 82-1 at 10. Relator responds that “[i]t seems far more likely that Allergan sought a release broad enough to swallow both actions, but the Government—aware that it was continuing to investigate these separate and distinct allegations—rejected Defendant’s efforts and insisted on language that made clear that the *Schwartz* matter has nothing to do with this pending case.” ECF 86 at 13-14 n.10. The Court is in no position to speculate about the Government’s state of mind during the *Schwartz* settlement negotiations. But whichever way the settlement agreement cuts, the two cases simply do not allege similar fraud schemes, and therefore, for the reasons stated above, the first-to-file bar does not apply.

makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]” 31 U.S.C. § 3729(a)(1)(A)-(B). To state a claim for FCA liability, the plaintiff must allege: “(1) the defendant made a false statement or engaged in a fraudulent course of conduct; (2) such statement or conduct was made or carried out with the requisite scienter; (3) the statement or conduct was material; and (4) the statement or conduct caused the government to pay out money or to forfeit money due.” *Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 913 (4th Cir. 2003). The scienter requirement under the FCA requires that a person act “knowingly” meaning that the defendant: “(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information[.]” 31 U.S.C. § 3729(b)(1)(A). However, to be found liable under the FCA, a defendant need not act with “specific intent to defraud[.]” 31 U.S.C. § 3729(b)(1)(B). Because FCA claims sound in fraud, they are subject to the pleading standard set forth in Federal Rule of Civil Procedure 9(b). *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783-84 (4th Cir. 1999). In the FCA context, Rule 9(b) requires the plaintiff to plead the “who, what, when, where, and how of the alleged fraud.” *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (internal quotations omitted). “Rule 9(b)’s heightened pleading standard [also] applies to state law fraud claims asserted in federal court.” *United States ex rel. Palmieri v. Alpharma, Inc.*, 928 F. Supp. 2d 840, 853 (D. Md. 2013) (quoting *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 13 (1st Cir. 2009)).

Relator’s FCA claims are predicated on Defendants’ alleged violation of the AKS. The AKS prohibits anyone from, in relevant part, “knowingly and willfully . . . offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) . . . to induce” a referral or purchase reimbursable “under a Federal health care program[.]” 42 U.S.C. § 1320a-7b(b)(2). “An AKS

violation that results in a federal health care payment is a per se false claim under the FCA.” *United States ex rel. Lutz v. United States*, 853 F.3d 131, 135 (4th Cir. 2017); 42 U.S.C. § 1320a-7b(g) (“[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31”). Under the AKS, Relator need only allege “that at least one purpose of the remuneration was to induce” referrals. *United States ex rel. Lutz v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021) (internal quotation marks omitted).

Relator’s theory is that Defendants violated the AKS, and consequently the FCA, by providing remuneration to bariatric surgeons in the form of free advertising to induce those surgeons to purchase the LAP-BAND device. *See* ECF 86 at 16-19. Because the remuneration was only provided if surgeons performed a certain number of LAP-BAND surgeries per year, the free advertising, in Relator’s view, induced surgeons to purchase more LAP-BANDs. *Id.* Defendants knew, according to Relator, that LAP-BAND surgeries are reimbursable by federal health care programs like Medicare, Medicaid, and Tricare (and, with respect to Relator’s state law claims, state health care plans), which require certifications that the transaction to be reimbursed complied with relevant laws and regulations, including the AKS. *See* ECF 86 at 6-7. Thus, Relator argues that by violating the AKS, Defendants caused false claims to be submitted to federal and state governments in violation of the FCA and state law equivalents. ECF 86 at 21.

This type of FCA claim is known as a presentment claim, which “arises when a claim for payment that is submitted to the government rests on a false representation of compliance with an applicable federal statute, federal regulation, or contractual term.” *United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498 (D.S.C. 2016) (*Lutz I*) (quoting *United States ex rel. Tran v. Computer Scis. Corp.*, 53 F. Supp. 3d 104, 122 (D.D.C. 2014)). Presentment claims

provide two avenues to plead that false claims were submitted: plaintiffs can either provide specific examples of false claims, or they can allege “a pattern of conduct that would ‘*necessarily* have led to submission of false claims’ to the government for payment.” *United States ex rel. Grant v. United Airlines, Inc.*, 912 F.3d 190, 197 (4th Cir. 2018) (emphasis in original) (quoting *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013)). Relator here argues he has done both. *See* ECF 86 at 21-22.

ii. Relator’s AKS Allegations

Relator argues he has met his burden to allege that Defendants (1) knowingly and willfully; (2) offered or paid remuneration; (3) with the intent to induce the referral of business or purchases; (4) reimbursable under a federal health care program. Defendants do not meaningfully contest that Relator has alleged the second or fourth elements of an AKS violation—Relator has alleged that providing free advertising and marketing to surgeons on the LAP-BAND website constitutes a form of remuneration, ECF 77 ¶ 10, and that LAP-BAND surgeries are reimbursable by federal health care programs, *see id.* ¶ 16. Defendants argue, however, that Relator has not alleged facts suggesting that Defendants acted “knowingly and willfully” or that the alleged remuneration was provided with the intent to induce the referral of business or purchases. To plead an AKS violation, Relator must allege facts to support his conclusion that Defendants acted “knowingly and willfully.” Knowingly means that the defendant acted with “knowledge of the facts that constitute the offense.” *United States ex rel. Lutz v. Berkeley HeartLab, Inc.*, No. 9:14-230-RMG, 2017 WL 5033652, at *3 (D.S.C. Oct. 31, 2017) (quoting *Bryan v. United States*, 524 U.S. 184, 192-93 (1998)). And “willfully” means that Defendants knew that their “conduct was unlawful,” that they were “acting ‘with a bad purpose,’” or that they knew they were acting “with evil intent without justifiable excuse.” *Id.* (quoting *Bryan*, 524 U.S. at 192-93).

Relator argues the facts alleged in the SAC meet this standard. Relator alleges that Defendants were familiar with the requirements of the AKS and knew the surgeons who appeared on the physician locator would be required to certify compliance with the AKS before submitting claims for reimbursement. ECF 86 at 16-17, 30; ECF 87 at 13-14. With respect to Allergan, Relator alleges that he specifically informed Allergan that its physician locator violated the AKS. ECF 86 at 30; ECF 77 ¶ 167. Further, Relator points to the SAC's allegations that Defendants "added surgeons to the referral service for *free*[,]” and that Allergan "kicked Relator off its website when he failed to sufficiently produce.” ECF 86 at 17 (emphasis in original). Relator also argues that the SAC alleges that "Allergan's workforce refused to discuss the program requirements in writing, opting only to discuss the matter with Dr. Fitzer by phone . . . [which, according to Relator,] suggests knowledge of the impropriety of its exclusive marketing scheme and desire not to create a paper trail.”³ *Id.* at 18. Finally, with respect to Apollo, Relator argues that its intent to act unlawfully can be inferred from the fact that it placed "disclosures on its website in an attempt to comply with one (and only one) of the four requirements of the referral service safe harbor.” ECF 87 at 14.

Even assuming, without deciding, that these allegations are sufficient to allege Defendants' "knowledge of the facts that constitute the offense[,]” none of them, individually or collectively, raises an inference that Defendants were acting willfully. The fact that Defendants were aware of the AKS and its requirements says nothing about whether they were acting with an unlawful intent while operating the LAP-BAND website. *See United States ex rel. Complin v. N.C. Baptist Hosp.*, No. 09-CV-00420, 2016 WL 7471311, at *14, *17 (M.D.N.C. Dec. 28, 2016) (refusing to infer

³ The SAC actually contains no factual allegations evidencing a refusal to discuss program requirements in writing. It simply describes a series of telephone discussions.

scienter based on relator's allegation that a hospital was, or should have been aware, of relevant laws and regulations that govern federal health care reimbursements), *report and recommendation adopted*, 2019 WL 430925 (M.D.N.C. Feb. 4, 2019). Similarly, neither the fact that Relator told Allergan that he believed the physician locator violated the AKS, nor the fact that Allergan decided to speak with Relator on the phone rather than in writing about that concern, indicates that Allergan was acting with malintent. Finally, Relator's allegation that Apollo's intent can be inferred from its posting of disclosures on the website describing the criteria for inclusion on the physician locator is merely Relator's own conclusion, not a factual basis upon which to infer Apollo's willfulness. Thus, none of these allegations supports Relator's conclusory assertions that Defendants knew they were acting unlawfully, "with a bad purpose," or "with evil intent without justifiable excuse." ECF 86 at 16 (quoting *Bryan*, 524 U.S. at 192-93).

Relator is undoubtedly correct that that "[t]o establish knowledge and willfulness at this early stage, relators 'need only allege a purpose to commit a wrongful act,' and need not yet demonstrate that the defendant did indeed act with that purpose." ECF 86 at 17 (quoting *Lutz I*, 225 F. Supp. 3d at 498). But Relator may not simply conclude that Defendants acted with an unlawful purpose; he must allege specific facts that support an inference that Defendants were, in reality, acting with that purpose. *Wilson*, 525 F.3d at 379 ("Although 'malice, intent, knowledge, and other conditions of a person's mind may be alleged generally,' an FCA plaintiff 'must still set forth specific facts that support an inference of fraud.'") (first quoting Fed. R. Civ. P. 9(b), then quoting *United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 385 (5th Cir. 2003)). The *Lutz* case, which Relator cites for the proposition that he "need only allege a purpose to commit a wrongful act," illustrates this distinction well. ECF 86 at 17 (quoting *Lutz I*, 225 F. Supp. 3d at 498). There, relators had alleged, *inter alia*, that the defendants had conducted

an unlawful scheme to pay physicians a fee for each referral they made for certain blood tests. *Lutz I*, 225 F. Supp. 3d at 496. But the relators had alleged specific facts to support their allegations that defendants had acted willfully—they had not just concluded as much. For example, relators pointed to specific efforts by the defendants to disguise illegal payments as lawful fees. *Id.* at 500. While the relators certainly had not yet *proven* the defendants’ intent, they made factual allegations to support their conclusion that defendants had acted willfully. Relator here, by contrast, has not done so; instead, he takes facts that are not necessarily indicative of the Defendants’ willfulness, and then asks the Court to credit his conclusions that they are. But because the conclusory allegations raise a mere *possibility*, rather than a *plausibility*, that the Defendants acted willfully, the Court must grant Defendants’ Motions. *Iqbal*, 556 U.S. at 678.

For similar reasons, the SAC also fails to allege facts to support Relator’s conclusion that Defendants acted with intent to induce referrals—the third element of an AKS violation. As Relator argues, he “alleges at least one purpose of Defendant[s]’ exclusive website marketing scheme was to increase the number of LAP-BAND procedures performed and therefore its own sales.” ECF 86 at 18-19 (citing ECF 77 ¶ 210-11). But that is a legal conclusion unsupported by any factual allegations.⁴ To be sure, Relator disagrees with Defendants’ consistently stated

⁴ The only factual allegation to which Relator points as apparent support for his assertion that Defendants acted with “intent to induce referrals” is his allegation that, at some point before July, 2015, Apollo expanded the criteria for inclusion on the physician locator to include some non-surgeons whom it described as LAP-BAND “specialists,” including Dr. Vivek Kumbhari. ECF 87 at 17; ECF 77 ¶ 199-204. Relator asserts that this expansion was indicative of Apollo’s intent to use the physician locator to drive LAP-BAND sales, ECF 87 at 17, but he fails to allege any facts to support that conclusion. The fact that the expanded criteria apparently allowed non-surgeons like Dr. Kumbhari to appear on the locator does not indicate Apollo’s intent to boost LAP-BAND sales—after all, Dr. Kumbhari did not purchase LAP-BANDs because he did not perform LAP-BAND surgeries. *Id.* And although Relator suggests that Apollo had a financial motive to include Dr. Kumbhari so that it could boost sales of *another* device Apollo sold (used in a separate procedure Dr. Kumbhari performed), Apollo’s alleged financial motive to sell that other device indicates nothing about its intent to increase referrals for LAP-BAND sales.

explanation that the purpose of the quota for inclusion on the physician locator, and the purpose of the locator tool more generally, is to match patients with surgeons who have experience implanting the LAP-BAND device. In Relator's view, that justification is "pretext" for a fraudulent scheme to sell more LAP-BANDs. Relator could be right, but he alleges no specific facts to support his conclusory assertion that Defendants enacted the quotas, even in part, to increase procedures performed.

iii. Relator's FCA and State Law Claims

Relator's theory of liability under the FCA, and state law equivalents, depends entirely on his claims that the Defendants violated the AKS. The parties dispute a number of legal questions central to Relator's FCA claims, including: whether an AKS violation must be the "proximate" or "but for" cause of a false claim in order to establish FCA liability; whether Relator pleads the alleged FCA violations with the requisite particularity (including, for example, whether physicians other than Dr. Fitzner even knew they were on the physician locator, and whether they received any benefit from it); whether Relator has sufficiently alleged that specific false claims were presented, or that Defendants engaged in "a pattern of conduct that would '*necessarily* have led to submission of false claims' to the government for payment[.]" *Grant*, 912 F.3d at 197 (emphasis in original) (quoting *Nathan*, 707 F.3d at 457); and whether the SAC's allegations demonstrate that Apollo complied with the AKS's safe-harbor provisions. Each of these issues raise significant questions about the viability of Relator's FCA claims. However, because the Court finds that the SAC does not, in the first instance, raise a plausible inference that Defendants violated the AKS, the Court need not reach the additional issues. If Relator seeks within forty-five days to amend the SAC to state a plausible AKS violation, the Court will address the additional issues to the extent they remain relevant.

IV. CONCLUSION

For the reasons set forth above, Defendants' Motions to Dismiss, ECF 80, 82, will be GRANTED. A separate order follows.

Dated: September 10, 2021

_____/s/
Stephanie A. Gallagher
United States District Judge